Signature

AF/ 16447

December 2, 2003

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Sperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## **TRANSMITTAL FORM**

(to be used for all correspondence after initial filing)

| Application Number     | 09/214,881        |  |  |
|------------------------|-------------------|--|--|
| Filing Date            | June 7, 1999      |  |  |
| First Named Inventor   | Ozaki             |  |  |
| Group Art Unit         | 1644              |  |  |
| Examiner Name          | Patrick Nolan     |  |  |
| Attorney Docket Number | 13240.0004.NPUS00 |  |  |

| Total Number of Pages in This Submission Attorney Docket Number 13240.0004.111 8300  |   |     |   |   |   |
|--|---|-----|---|---|---|
| ENCLOSURES (check all that apply)  |   |     |   |   |   |
| Fee Transmittal For  | m   |     | Assignment Papers (for an Application)                      |   | After Allowance Communication to Group                            |
| Fee Attached   | d   |     | Drawing(s)  |   | Appeal Communication to Board of Appeals and Interferences        |
| Amendment / Reply  | <i>'</i>  |     | Licensing-related Papers                                    | s | Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) |
| After Final  |   | Щ   | Petition  |   | Proprietary Information   |
| Affidavits/de  | claration(s)  |     | Petition to Convert to a<br>Provisional Application         |   | Status Letter   |
| Extension of Time F  | Request   |     | Power of Attorney, Revo<br>Change of Corresponde<br>Address |   | Other Enclosure(s) (please identify below):                       |
| Express Abandonm   | ent Request   |     | Terminal Disclaimer  Request for Refund                     |   | PTO Form-1449w/cited references;                                  |
| Information Disclose   | ure Statement   |     | CD, Number of CD(s) _                                       |   | Postcard  |
| Certified Copy of Pr<br>Document(s)  | iority  | Rem | arks  |   | DEC 1 0 2003  |
| Response to Missin Incomplete Applicat   | lissing Parts/  |     |   |   | TECH CENTER 1600/2900   |
|  | Missing Parts<br>R 1.52 or 1.53   |     |   |   |   |
| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT   |   |     |   |   |   |
| Firm<br>or<br>Individual name  | Christopher J. Buntel, Ph.D.; Howrey Simon Arnold & White, LLP<br>Reg. No. 44,573; Customer No. 23369 |     |   |   |   |
| Signature Control Cont |   |     |   |   |   |
| Date   | December 2, 2003  |     |   |   |   |
| CERTIFICATE OF MAILING   |   |     |   |   |   |
| I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450; on this date:  12/02/03  |   |     |   |   |   |
| Typed or printed name Christopher J. Buntel, Ph.D.   |   |     |   |   |   |

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Date

PTO/SB/17 (10-03) Approved for use through 07/31/2006. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Und the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Complete if Known **TRANSMITTAL** 09/214,881 Application Number Filing Date June 7, 1999 for FY 2004 Shoichi Ozaki First Named Inventor Effective 10/01/2003. Patent fees are subject to annual revision. Patrick Nolan Examiner Name Applicant claims small entity status. See 37 CFR 1.27 1644 Art Unit (\$) 180.00**TOTAL AMOUNT OF PAYMENT** 13240.0004.NPUS00 Attorney Docket No FEE CALCULATION (continued) METHOD OF PAYMENT (check all that apply) Money Order 3. ADDITIONAL FEES Check Credit card Other None Large Entity | Small Entity Deposit Account: Fee Fee **Fee Description** Deposit Code (\$) Code (\$) Fee Paid 01-2508/13240.0004.NPUS00 Account 1051 130 2051 65 Surcharge - late filing fee or oath Number Deposit Surcharge - late provisional filing fee or 1052 50 2052 Howrey Simon Arnold & White LLP Account cover sheet Name 1053 130 1053 130 Non-English specification The Director is authorized to: (check all that apply) 1812 2,520 1812 2,520 For filing a request for ex parte reexamination Charge fee(s) indicated below Credit any overpayments Requesting publication of SIR prior to 1804 920 1804 920\* Charge any additional fee(s) or any underpayment of fee(s) Examiner action Charge fee(s) indicated below, except for the filing fee 1805 1,840 1805 1,840° Requesting publication of SIR after to the above-identified deposit account. Examiner action 1251 110 2251 Extension for reply within first month **FEE CALCULATION** 1252 420 2252 210 Extension for reply within second month 1. BASIC FILING FEE 1253 950 2253 475 Extension for reply within third month arge Entity Small Entity Fee Paid Fee Fee Code (\$) Fee Fee Description 2254 1254 1.480 740 Extension for reply within fourth month Code 1,005 Extension for reply within fifth month 1255 2.010 2255 1001 770 2001 385 Utility filing fee 1401 330 2401 165 Notice of Appeal 1002 340 2002 170 Design filing fee 1402 330 2402 165 Filing a brief in support of an appeal 1003 530 2003 265 Plant filing fee 1403 290 2403 145 Request for oral hearing 1004 770 2004 385 Reissue filing fee 1005 160 2005 Provisional filing fee 1451 1,510 1451 1,510 Petition to institute a public use proceeding 1452 110 2452 55 Petition to revive - unavoidable SUBTOTAL (1) (\$) 1453 1.330 2453 665 Petition to revive - unintentional 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE 665 Utility issue fee (or reissue) 1501 1 330 2501 Fee from Extra Claims Fee Paid 1502 480 2502 240 Design issue fee below **Total Claims** х -20\*\* = 1503 640 2503 320 Plant issue fee Independent 130 Petitions to the Commissioner 1460 130 1460 Multiple Dependent 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 180,00 Large Entity Small Entity 1806 180 1806 180 Submission of Information Disclosure Stmt **Fee Description** 40 Recording each patent assignment per Code (\$) Code (\$) 8021 40 8021 property (times number of properties) Claims in excess of 20 1202 18 2202 9 385 Filing a submission after final rejection 1809 770 2809 Independent claims in excess of 3 1201 86 2201 43 (37 CFR 1.129(a)) 1203 290 Multiple dependent claim, if not paid 2203 145 1810 770 2810 385 For each additional invention to be examined (37 CFR 1.129(b)) \*\* Reissue independent claims 1204 86 2204 43 over original patent 1801 770 2801 385 Request for Continued Examination (RCE) Request for expedited examination 1205 2205 9 \*\* Reissue claims in excess of 20 1802 900 1802 18 and over original patent of a design application Other fee (specify) (\$) SUBTOTAL (2) \*Reduced by Basic Filing Fee Paid SUBTOTAL (3) 180.00 (\$) \*\*or number previously paid, if greater; For Reissues, see above (Complete (if applicable)) SUBMITTED BY Registration No. Name (Print/Type) Christopher J. Buntel, Ph.D. 44,573 Telephone 713,787,1569 Date December 2, 2003 Signature

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PROPERTY OF THE PROPERTY OF T

In re Application of: Ozaki et al.

Serial No.: 09/214,881

Examiner: Patrick Nolan

Confirmation No.: 8089

Att'y Docket: 13240.0004.NPUS00

Filed: June 7, 1999

Client Docket: F5-01F03832/KA016-1US RCE

For: DIAGNOSTIC DRUGS FOR AUTO

**IMMUNE DISEASES** 

## INFORMATION DISCLOSURE STATEMENT

CERTIFICATE OF MAILING 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

December 2, 2003

Signature

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

12/05/2003 SSITHIB1 00000147 012508 180.00 DA 01 FC:1806

In accordance with 37 C.F.R. § 1.97(e), Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was not known to Applicant more than three months from the filing of the present statement, and was cited in a communication from a foreign patent office in a counterpart foreign application received not more than three months prior to the filing of the present statement, as evidenced by the date of receipt of the enclosed European Examination Report.

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180 is enclosed. A Fee Transmittal form is enclosed authorizing the Commissioner to deduct the above fee from Howrey Simon Arnold & White, LLP Deposit Account 01-2508/13240.0004.NPUS00/BNT.

Applicant respectfully requests that the listed documents be made of record in the present case.

Respectfully submitted,

Christopher J. Buntel, Ph.D.

Reg. No. 44,573

Customer No. 23369

ATTORNEY FOR ASSIGNEE, KANEKA CORPORATION

Howrey Simon Arnold & White, LLP 750 Bering Drive Houston, TX 77057-2198 (713) 787-1569

December 2, 2003

ich or Children on on one of the children one of the children on one of the children one of the children one of th Page 1 of 1 Serial No. Atty. Docket No. 700Forth PTO-1449 (modified) 09/214,881 13240.0004.NPUS00 of Patents and Publications for Applicant's **Applicant** Ozaki et al. INFORMATION DISCLOSURE STATEMENT Filing Date: Group: (Use several sheets if necessary) June 7, 1999 1644 **U.S. Patent Documents Foreign Patent Documents** Other Art

N/a

## Other Art (Including Author, Title, Date, Pertinent Pages, Etc.)

N/A

See Page 1

| Exam.<br>Init. | Ref.<br>Des. | Citation   |
|----------------|--------------|--|
|                | Cl           | European Examination Report; August 28, 2003   |
|                | C2           | "Anti-Neutrophil cytoplasmic antibodies (ANCA) in ulcerative colitis; anti-cathepsin G and a novel antibody correlate with a refractory type;" J. Sobajima, S. Ozaki, T. Okazaki, F. Osakada, S. Sumita, K. Mori & K. Nakao; 1996 Blackwell Science Ltd, Clinical and Experimental Immunology; pp. 120-124 |
|                | C3           | "Antineutrophil cytoplasmic autoantibodies, autoantigens, and systemic vasculitis;" Wolfgang L. Gross, Elena Csernok and Udo Helmchen; 1995 APMIS 103, pp. 81-97   |
|                | C4           |  |
|                | C5           |  |
|                | C6           |  |
|                | C7           |  |
|                | C8           |  |
|                | С9           |  |
|                | C10          |  |
|                | C11          |  |
|                | C12          | •  |
|                | C13          |  |
|                | C14          |  |
|                | C15          |  |
|                | C16          |  |
|                | C17          |  |
|                | C18          |  |
|                | C19          |  |
|                | C20          |  |

| Examiner: | DATE CONSIDERED: |
|-----------|------------------|

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.